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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,576	07/17/2003	Andreas Dieckmann	1506-1035-1	8464

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,576	DIECKMANN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-16, 23-25 drawn to a compound targeted to a nucleic acid encoding neutrophil gelatinase associated lipocalin (NGAL), classifiable in class 536, subclass 24.5. This group is subject to a further restriction as per below.

II. Claims 17-22, 26-27 and 30, drawn to a method of inhibiting the expression of NGAL and a method of treating a patient comprising administering an oligonucleotide targeted to a nucleic acid encoding NGAL, classifiable in class 514, subclass 44.

III. Claims 28-29 and 38-39, drawn to a transgenic non-human animal wherein the animal carries at least one sequence encoding NGAL, classifiable in class 800, subclass 3.

IV. Claim 33, drawn to a method of screening for expression of NGAL, classifiable in class 435, subclass 6.

V. Claim 32-37, drawn to a method compound targeted to a nucleic acid molecule encoding 24p3/uterocalin, classifiable in class 435, subclass 6. This group is subject to further restriction as per below.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I and group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product compound of group I can be used as a probe in *in situ* hybridization assays, which is materially different than the methods of inhibiting expression of a target gene and a method of treating a patient comprising administering an antisense compound to cells, tissues or whole animals, as present in group II. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the compound of group I functions to bind to a target nucleic acid sequence and is not involved in generation of a transgenic non-human animal that has an antisense sequence incorporated into the genome, as present in group III. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the compound of group I functions to bind to a target nucleic acid sequence and is not involved in the method of screening for the presence or absence of NGAL, as present in group IV, which comprises determining an effective amount of NGAL in cells, tissues or whole animals and determining a detection technique. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different modes of operation with different effects. For example, the compound of group I and the compound of group V are structurally and functionally independent because each compound has a unique sequence and each compound targets a different gene. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the method of inhibiting expression of NGAL and the method of treating a patient comprising administering an antisense compound targeted to a nucleic acid gene expressing NGAL of group II is not involved with generation of a non-human transgenic animal that incorporates an antisense sequence in the genome. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the method of inhibiting expression of MMP-12 and the method of treating a patient comprising administering an antisense compound targeted to a nucleic acid gene expressing NGAL of group II is not involved with the method of screening for the presence or absence of expression of NGAL, which comprises determining an effective amount of NGAL in cells, tissues or whole animals and determining a detection technique. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the method of inhibiting expression of NGAL and the method of treating a patient comprising administering an antisense compound targeted to a nucleic acid gene expressing NGAL of group II does involve with the compound of group V, which functions to target a nucleic acid sequence encoding 24p3/uterocalin. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the transgenic non-human animal of group III involves incorporation of an antisense sequence into the genome of the animal and is not involved in determining efficient levels of NGAL in cells or tissues and determining an efficient detection technique, as present in the method of screening for the presence or absence of expression of NGAL of group IV. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the transgenic non-human animal of group III involves incorporation of an antisense sequence into the genome of an animal which is not involved with the product compound of group V, which functions to bind to a target nucleic acid sequence. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because they are drawn to materially different methods with different effects. For example, the method of screening for the presence or absence of NGAL, as present in group IV, involves determining efficient levels of NGAL in cells or tissues and determining a detection technique and does not involve the product compound of group V, which functions to bind to a target nucleic acid sequence. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, should applicants elect to prosecute Group I or Group V, these Groups are subject to further restriction as follows. Claims 6-7 of Group I and claim 37 of Group V are subject to an additional restriction since they are not considered to be proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claim 6 and 7 specifically claim oligonucleotide SEQ ID NOS 3-11, which are targeted to and modulate the expression of NGAL. Although the oligonucleotide sequences claimed each target and modulate expression of NGAL, the instant oligonucleotide sequences are considered

to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence, each oligonucleotide sequence targets a different and specific region of NGAL nucleic acid, and each oligonucleotide, upon binding to NGAL nucleic acid, inhibits the expression of the gene and to varying degrees (per specification, page 25 lines 22-28). As such the Markush/genus of oligonucleotide sequences in Claims 3 and 4 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claims 6 and 7 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) oligonucleotide sequence from claims 6 and 7. Note that this is not a species election.

Claim 1 link(s) inventions 6 and 7. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 37 of Group V specifically claim oligonucleotide SEQ ID NOS 3-11, which are targeted to and modulate the expression of 24p3/uterocalin. Although the oligonucleotide sequences claimed each target and modulate expression of 24p3/uterocalin, the instant oligonucleotide sequences are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence and each oligonucleotide sequence targets a different and specific region of 24p3/uterocalin nucleic acid, and each oligonucleotide. As such the Markush/genus of oligonucleotide sequences in claim 37 is not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claim 37 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) oligonucleotide sequence from claim 37. Note that this is not a species election.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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Kimberly Chong
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1635